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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,419

10/15/2007

Alain H. Curaudeau

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MORRISON & FOERSTER LLP
12531 HIGH BLUFF DRIVE
SUITE 100
SAN DIEGO, CA 92130-2040

EXAMINER

JAGOE, DONNA A

ART UNIT

PAPER NUMBER

1614

MAIL DATE

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09/02/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,419	Applicant(s) CURAUDEAU ET AL.	
	Examiner Donna Jagoe	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-19 and 22 is/are pending in the application.
- 4a) Of the above claim(s) 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/5/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments filed May 5, 2009 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-9, 11-19 and 22 are pending in this application. Claim 22 is withdrawn.

Newly submitted claim 22 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: applicant was directed to elect a single photosensitizer for search and examination. As detailed in the office action dated January 5, 2009, a search was made on the photosensitizer verteporfin. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 22 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Priority

Receipt is acknowledged of CA 2457214 submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 and 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Candela Corporation WO 2003/086460 A2 in view of Olive Oil Chemistry (U) Bershad U.S. Patent No. 6,096,765.

Candela Corp. teaches a method of treating oily skin and sebaceous hyperplasia (pages 16-17, paragraph 55) comprising topical application of by photodynamic activation of photosensitizers in the skin region affected by the conditions (paragraph 1). Regarding the topical application of hydrophobic and/or lipophilic photosensitizer compositions to the skin, Candela Corp. teaches examples of the photosensitizer mixed in a liposome formulation (see example 6, paragraph 72) and in olive oil (example 15 paragraph 84). Liposome formulations are lipophilic and olive oil is hydrophobic. Photosensitizers useful in the practice of the invention include, for example, chlorins, cyanines, purpurins and porphyrins, for example, benzoporphyrin derivative monoacid (BPD-MA) (also known as verteporfin (paragraph 77)). Other useful photosensitizers include, for example, bacteriochlorins and bacteriopurpurins, such as those described in U. S. Patent No. 6,376, 483 B1, for example 5,10-octaethylbacteriopurpurin, and 5,15-octaethylbacteriopurpurin, or nickel 5, 10-bis-acrylate etioporphyrin 1. Other useful photosensitizers include xanthenes, for example, rose bengal, or other photosensitizers that may be isolated or derived from natural sources, or synthesized de novo. (page 8, paragraph 25). Energy sources are applied at a wavelength capable of activating the photosensitizer (paragraphs 41-47). The beam of light has a fluence rate of between about 100 W/cm² and about 40 mW/cm² (page 4, paragraph 0012) which partially overlaps and encompasses the claimed fluence rate of between 0.1mW/cm² to about

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600 mW/cm². In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). The compositions are administered topically (paragraph 32). The treatment includes removal of keratotic layers by application of a descaling agent, e.g. salicylic acid or by administration of a drug, for example a topical drug to the lesion (paragraph 56). Suitable light sources include a pulsed diode laser (addressing instant claim 18) (paragraph 40-41). Candela Corp. teaches that both red and blue light have been used in ALA photodynamic therapy (paragraphs 3 and 5).

Regarding the viscosity, Candela Corporation does not teach a specific viscosity, however, for example, when combined with olive oil the viscosity would be 84 centipoise (cP) and 20°C which is encompassed in the claimed range of 50 to 50,000 cps.

Regarding the viscosity of olive oil, the following information is relied on for support of the viscosity of olive oil. See OliveOilSource/Olive Chemistry (U).

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Density or Specific Gravity:	0.9150-0.9180 @ 15.5 °C
Viscosity:	84 mPa.s (84 cP) at 20 Degrees Celsius
Specific Heat:	2.0 J/(g.) (Degree Celsius) or .47 Btu/(lb.) (°F)
Thermal Conductivity:	@ 20 degrees Celsius - 0.17
Dielectric constant, ϵ , @ 20°C	3.1
Density @ 20 Degrees Celsius:	920 kg/m ³ or 7.8 lbs/U.S. Gal
Volumetric Heat Capacity @ 20 Degrees Celsius:	1.650 10 ⁶ J/m ³
Thermal Diffusivity @ 20 Degrees Celsius:	10 x 10 ⁻⁸ m ² /s
Boiling Point:	570 degrees
Calories per tablespoon olive oil:	Fahrenheit about 120 calories

Regarding the removal of the excess photosensitizer, Candela Corp. teaches that the excess emulsion is removed from the lesion surface (paragraph 70). See also the examples wherein the excess emulsion is removed. Regarding the method wherein the treatment steps are repeated at least once every six months, at least once every 3 months, and repeated in intervals of not less than 5 days, Candela Corp. teaches that the procedure can be repeated as necessary (see example 18 paragraph 87).

Regarding the topical application of other agents, such as topical retinoids, Candela Corp teaches additional treatment with topical salicylic acid or another topical drug for descaling the lesion (paragraph 56). It does not teach topical retinoids. Bershad teaches treatment of acne with topically applied retinoid compositions (see abstract).

It is prima facie obvious to substitute equivalents, motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. *In re Ruff* 118 USPQ 343; *In re Jezel*

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158 USPQ 99; the express suggestion to substitute one equivalent for another need not be present to render the substitution obvious. *In re Font*, 213 USPQ 532. Candela Corp. showed the method of treatment of PDT with porphyrin agents such as verteporfin for acne and additionally topical salicylic acid. Therefore, it would have been obvious to one of ordinary skill in the art to substitute the salicylic acid taught in Candela Corp. for the topical retinoids of Bershad for the predictable result of descaling the acne lesions.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Response to Arguments

Applicant asserts that Candela does not teach a method to treat hyperactive sebaceous gland disorders other than acne in a subject by (i) topically applying a hydrophobic and/or lipophilic photosensitizer composition to skin tissue exhibiting symptoms of a hyperactive sebaceous gland disorder, and (ii) exposing the tissue of said subject to light energy at a wavelength capable of activating the photosensitizer and at a fluence rate between about 0.1 mW/cm² and about 600mW/cm², wherein said photosensitizer is other than 5-aminolevulinic acid and derivatives thereof and further asserts that "Olive" does not teach a method to treat hyperactive sebaceous gland disorders other than acne in a subject by (i) topically applying a hydrophobic and/or lipophilic photosensitizer composition to skin tissue exhibiting symptoms of a

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hyperactive sebaceous gland disorder, and (ii) exposing the tissue of said subject to light energy at a wavelength capable of activating the photosensitizer and at a fluence rate between about 0.1 mW/cm^2 and about 600 mW/cm^2 , wherein said photosensitizer is other than 5-aminolevulinic acid and derivatives thereof. In response, In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant should submit an argument under the heading "Remarks" pointing out disagreements with the examiner's contentions. Applicant must also discuss the references applied against the claims, explaining how the claims avoid the references or distinguish from them.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Donna Jagoe /D. J./
Examiner
Art Unit 1614

August 29, 2009

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614